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Pre-operative short-course radiotherapy versus neoadjuvant radiochemotherapy in locally advanced rectal cancer (uT2N+, uT3N-/+)

Submission date 25/05/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 02/07/2007	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 04/01/2021	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.rrk-berlin.de/rrkweb/chirurgie/cco/forschung/forschungsschwerpunkte/Rektumstudie.pdf

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2004-001606-27

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Pre-operative short-course radiotherapy versus neoadjuvant radiochemotherapy in locally advanced rectal cancer (uT2N+, uT3N-/+)

Acronym
BRCT (Berlin Rectal Cancer Trial)

Study objectives
Standard treatment for locally advanced cancer of the rectum is pre-operative short-course radiotherapy or combined neoadjuvant radiochemotherapy with 5-fluorouracil (5-FU) plus post-operative chemotherapy with 5-FU. Similar long-term survival, local control and late morbidity have been reported for both these methods in non-comparative studies. In addition to other ongoing comparative trials we include a larger number of patients for adequate power and we avoid the adjuvant treatment bias by mandatory adjuvant chemotherapy in both groups. It is our hypothesis that the rate of local recurrence after five years is 12% in pre-operative short-course radiotherapy and 7% in combined radiochemotherapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Ethics Committee of the Charité and the responsible authorities. Certified and recommended by the German Gancer Society ("Gütesiegel A") on the 29th September 2003 (ref: AA3/03/38; EudraCT-number: 2004-001606-27).

Study design
Randomised controlled multicentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Rectal cancer

Interventions
Group one: receiving pre-operative short-course radiotherapy (five times 5 Gy) followed by total mesorectal excision (TME) and adjuvant continous 5-FU infusion therapy for 12 weeks.
Group two: receiving neoadjuvant combined radiochemotherapy (50.4 Gy and continuous 5-FU) followed by TME and adjuvant continous 5-FU infusion therapy for 12 weeks.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
5-fluorouracil (5-FU)

Primary outcome measure
Local recurrence, median follow up five years

Secondary outcome measures
1. Overall survival, median follow up five years
2. Disease-free survival, median follow up five years
3. Complete resection rate (R0 resection): measured at the date of surgery of the last patient entered
4. Rate of sphincter saving resection: measured at the date of surgery of the last patient entered
5. Acute and late toxicity (radiation related side effects), median follow up five years
6. Quality of life including long term bowel function, median follow up five years

Overall study start date
15/01/2004

Completion date
31/12/2009

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Karnofsky Index 80% or better
3. Histological diagnosis of adeno- or mucinous carcinoma of rectum
4. Primary rectal cancer:
4.1. Maximum 12 cm above dentate line (upper limit)
4.2. Staged T2N+ or T3N0 or T3N+ (by endorectal ultrasound or computed tomography [CT] /magnetic resonance imaging [MRI] scan)
5. No evidence of metastatic disease as determined by chest X-ray and abdominal ultrasound (or CT-scan of chest and abdomen or other investigations such as positron emission tomography [PET] scan or biopsy if required)

6. Adequate bone marrow function with platelets more than 100 x 10^9/l and neutrophils more than 2.0 x 10^9/l
8. Creatinine clearance more than 50 ml/min
7. Serum bilirubin less than 2.0 x upper limit of institutional normal range (ULN)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
760 patients (380 group one, 380 group two)

Key exclusion criteria
1. Rectal cancer other than adeno- or mucinous carcinoma
2. Previous or concurrent malignancies, with the exception of adequately treated basal cell carcinoma of the skin or in situ carcinoma of the cervix
3. Patients with locally advanced inoperable disease, such as T4-tumour
4. Presence of metastatic disease or recurrent rectal tumour
5. Any previous chemotherapy or radiotherapy, and any investigational treatment for rectal cancer
6. Concurrent uncontrolled medical conditions
7. Pregnancy or breast feeding
8. Clinically significant (i.e., active) cardiac disease (e.g., congestive heart failure, symptomatic coronary artery) or myocardial infarction within the last six months
9. Stenotic tumour which can not be passed by the colonoscope and pre-operative need of diverting stoma
10. Evidence of hereditary colorectal cancer (hereditary non-polyposis colorectal cancer [HNPCC] and familial adenomatous polyposis [FAP])
11. Medical or psychiatric conditions that compromise the patients ability to give informed consent

Date of first enrolment
15/01/2004

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
Austria

Germany

Study participating centre
Department of Surgery and Surgical Oncology
Berlin
Germany
D-13125

Sponsor information

Organisation
Berlin Cancer Society (Berliner Krebsgesellschaft e.V.) (Germany)

Sponsor details
Kaiserin-Friedrich-Haus
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Sponsor type
Research organisation

Website
http://www.berlinerkrebsgesellschaft.de

ROR
https://ror.org/020yxp837

Funder(s)

Funder type
Research organisation

Funder Name
Berlin Cancer Society (Berliner Krebsgesellschaft e.V.) (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	06/02/2009	04/01/2021	Yes	No